IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Matter of US Application No. 10/553,462

Considered

/AKS/ 2/4/2009

DECLARATION OF DR MATTHEW ROSE

I, Dr Matthew Rose, of Unipath Limited, Bedford United Kingdom, do hereby declare as follows:

1. I have read the specification of this application. It contains a written description of the invention as now claimed in full, clear, concise and exact terms as to enable any person skilled in the art to use the invention. In particular, a person skilled in the art would be able, based on the disclosure of the specification as originally filed, to identify that a pregnant woman at a stage of pregnancy from 4 to 25 weeks gestation is at risk of developing pre-eclampsia or that her fetus is at risk of developing intrauterine growth restriction (IUGR) by determining that her ADMA level is greater than 1.5 μmol/L.

2. All of the statements concerning enablement made in the last response that was filed in connection with this application are true. In the interest of brevity, those statements will not be repeated here.

2. The key point in relation to enablement is that the invention requires determining that a pregnant woman is at risk of developing pre-eclampsia or her fetus is at risk of developing IUGR. In other words, as explained at page 3, lines 26 to 30 of the specification, the invention concerns identifying those women who are susceptible to pre-eclampsia or those fetuses that are susceptible to IUGR. Essentially, the invention is a "risk test". Women who display an ADMA level greater than 1.5 μmol/L at 4 to 25 weeks gestation will be placed in a high risk bracket and monitored further for any signs of pre-eclampsia or IUGR.

3. The invention does not, as the Examiner seems to be suggesting, require diagnosing pre-eclampsia or IUGR. In other words, the invention is not a "diagnostic test".